MEMORANDUM

BlueCross BlueShield Association

An Association of Independent Blue Cross and Blue Shield Plans

Date: December 5, 2016

To: The Honorable Phyllis C. Borzi
Assistant Secretary of Labor
Employee Benefits Security Administration

From: Kris Haltmeyer
Vice President
Health Policy Analysis
Blue Cross Blue Shield Association

RE: Proposed Revision of Annual Information Return/Reports (Form 5500) RIN 1210–AB63

Attached are two comment letters on the Proposed Revision of Annual Information Return/Reports (Form 5500), RIN 1210–AB63.

- *Overhaul of Form 5500:* The first comment letter covers a range of issues raised by the Proposed Revision, emphasizing that the agencies should ease the burden of reporting by, for example, not collecting unnecessary information and recognizing that health insurance issuers may not have certain kinds of information.

- *Schedule J and All Payer Claims Database ("APCD") Issues:* The second comment letter responds to the request for comments by the agencies on the proposed new reporting requirements in light of *Gobeille v. Liberty Mutual Insurance Company.* It addresses whether the agencies should use the Form 5500 to collect typical APCD data and provide it to the states that have APCDs. This comment letter emphasizes that use of the Form 5500 for this purpose faces legal issues and is not good public policy due to the imposition of significant administrative burdens and costs and the inability to assure the integrity of data.

Your consideration of these comment letters is appreciated.

Attachments

BlueCross BlueShield Association

An Association of Independent Blue Cross and Blue Shield Plans

December 5, 2016

The Honorable Phyllis C. Borzi
Assistant Secretary of Labor
Office of Regulations and Interpretations
Employee Benefits Security Administration
Attn: RIN 1210–AB63
Annual Reporting and Disclosure
Room N–5655
U.S. Department of Labor
200 Constitution Avenue, N.W.
Washington, DC 20210

Submitted via regulations.gov

RE: Proposed Revision of Annual Information Return/Reports (Form 5500) RIN 1210–AB63

Dear Secretary Borzi:

The Blue Cross and Blue Shield Association ("BCBSA") appreciates the opportunity to provide comments to the Department of Labor ("DOL"), as well as the Department of the Treasury and the Pension Benefit Guaranty Corporation (collectively, the "Agencies") on the Proposed Revision of Annual Information Return/Reports (Form 5500), 81 Fed. Reg. 47534 (July 21, 2016) ("Proposed Revisions").

BCBSA is a national federation of 36 independent, community-based, and locally operated Blue Cross and Blue Shield Plans ("Plans") that collectively provide health care coverage for more than 106 million – one in three – Americans. Blue Cross and Blue Shield Plans offer coverage in every market and every ZIP Code in America. Plans also partner with the Government in Medicare, Medicaid, the Children's Health Insurance Program, and the Federal Employees Health Benefits Program.

The Proposed Revisions greatly expand the reporting required of group health plans. The Proposed Revisions would impose significant administrative burdens and costs on employers – especially small employers – and their service providers to provide new information, sometimes in response to vague questions (*e.g.,* "Is the coverage provided by the plan in compliance with [name of complex legislation] and the Department's regulations thereunder?").

This expansion is unnecessary and presents a substantial challenge to Plans to provide services to their customers to assist with reporting in an efficient, practical, and cost-effective manner. The Proposed Revisions should be streamlined to reduce the scope of information reported, require easily identifiable information and provide clear instructions on required information to ease the impact and administration of the reporting requirements.

Key Recommendations

Our key recommendations are as follows:

- *Indirect Compensation:* The Agencies should make explicit in the instructions and preamble to the final Form 5500 revisions that there is no obligation to report indirect compensation that is earned by service providers to ERISA-covered welfare plans.

- *Volume and Scope of Information Required:* The Agencies should prioritize the information they need and reduce the amount of information collected to ease the substantial new burdens placed on group health plan filers (especially small employers) and their service providers.

- *Benefit Claims Processing and Payment:* The Agencies should incorporate the definitions related to claims from the National Association of Insurance Commissioners' Market Conduct Annual Statement.

- *Reporting Premium Delinquencies and Coverage Lapses:* The requirement to report insurance premium delinquencies and lapses in coverage should be eliminated or substantially scaled back because the costs associated with gathering and reporting this information will greatly exceed its usefulness.

- *COBRA Information:* The Agencies should recognize that group health insurance issuers and third-party administrators ("TPAs") will often have little to no information on COBRA enrollees, especially for self-insured plans.

- *Identification of Service Provider as a Fiduciary:* The Agencies should make clear that the "yes" or "no" fiduciary identification box on Schedule C is required only for covered service providers within the meaning of the ERISA section 408(b)(2) disclosure regulation.

Additional recommendations and detailed comments are attached.

Further, we are submitting today a separate letter focusing on the specific solicitation for comments on the case of *Gobeille v. Liberty Mutual Insurance Company,* 577 U. S. ____, 136 S.Ct. 936 (March 1, 2016). *See* 81 Fed. Reg. 47534, 47559 (July 21, 2016).

We appreciate the opportunity to provide comments regarding the Proposed Revisions and look forward to continuing to work with the Agencies as they issue guidance on implementing revised employee benefit reporting. If you have any questions, please contact Richard White at Richard.White@bcbsa.com or 202.626.8613.

Sincerely,

Kris Haltmeyer
Vice President
Health Policy Analysis
Blue Cross Blue Shield Association

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BCBSA Detailed Comments and Recommendations on Proposed Revision of Annual Information Return/Reports (Form 5500)

I. Schedule C Reporting of Indirect Compensation to Welfare Plan Service Providers

Issue:

It is not entirely clear that the proposed revisions to Schedule C provide that there is no obligation to report indirect compensation received by service providers to welfare plans.

Recommendation:

The Agencies should make explicit in the instructions and preamble to the final Form 5500 revisions that there is no obligation to report indirect compensation that is earned by service providers to ERISA-covered welfare plans. Of course, this can be changed if the DOL promulgates a 408(b)(2) disclosure regulation that applies to service providers to welfare plans.

Rationale:

Plans often act as service providers to group health plans, generally when they act as a third party administrator to a self-insured group health plan. We have received a number of comments and questions from Plans regarding what impact the Proposed Revisions to Schedule C will have on service providers to group health plans. These questions relate to what types of indirect compensation is reportable for welfare plan service providers under the Proposed Revisions, and the obligations of welfare plan service providers to provide this information. For example, we have been asked what impact the elimination of the special reporting rule for "eligible indirect compensation" will have on the disclosures our member Plans provide to their customer ERISA-covered group health plans to support the plan's Form 5500 reporting obligation.

We support the Department's stated objective to harmonize the Schedule C reporting rules with the existing disclosure regime that DOL promulgated under ERISA section 408(b)(2). Currently, the 408(b)(2) disclosure obligations apply only to certain types of service providers to ERISA-covered pension plans. And when it promulgated the disclosure regulations under ERISA section 408(b)(2), DOL specifically stated that it was reserving applying the disclosure regulation to welfare plans, pending a specific regulatory review of welfare plan compensation arrangements. *See* 75 Fed. Reg. 41600, 41618 (Jul. 16, 2010). Although we strongly believe that DOL intended to eliminate the requirement to report indirect compensation earned by providers to welfare plans, it is not entirely clear that this is the result of DOL's Proposed Revisions to Schedule C. Because this is a critically important reporting issue for our member Plans, we ask DOL to make explicit in the Schedule C instructions and preamble to the final Form revisions that there is no requirement to report indirect compensation earned by a provider that provides services to an ERISA-covered welfare plan.

The reason for the lack of clarity on this fundamental point is that the language discussing the changes to Schedule C in the preamble and in the revised instructions to Schedule C itself is somewhat inconsistent and ambiguous. In the preamble, DOL states "the Schedule C would be changed to require reporting of indirect compensation only for "covered service providers" and

for compensation that is required to be disclosed, as defined in 29 CFR 2550.408b-2(c)(1)." 81 Fed. Reg. 47534, 47551 (Jul. 21, 2016). This language suggests that no indirect compensation must be reported on the Schedule C for service providers to welfare plans, because no indirect compensation is required to be disclosed by welfare plan service providers under DOL's current 408b-2 disclosure regulation. However, the proposed instructions themselves are more ambiguous. The revised Schedule C instructions provide a list of the types of providers who qualify as "covered services providers" under 29 C.F.R. § 2550.408b-2(c)(1)(iii). 81 Fed. Reg. at 47615. This citation does not clearly incorporate the fact that "covered service providers" are so identified only in connection with their relationships to "covered plans" defined in 29 C.F.R. § 2550.408b-2(c)(1)(ii). The proposed Schedule C instructions go on to provide that "Welfare plans are not subject to the service provider disclosure regulation at 29 CFR 2550.408b-2, but all plans, including welfare plans, that are required to file the Schedule C should use the provisions and definitions [of] 29 CFR 2550.408b-2 as a guide in completing the Schedule C." *Id.* It is this language creates confusion as to whether DOL intended for "covered services providers" within the meaning of the revised Schedule C to include, for example, the following types of providers *when they provide such services to a welfare plan*: fiduciaries, registered investment advisers, and persons who provide accounting, auditing, actuarial, banking, consulting, custodial, and other specified services for indirect compensation.

Because this is such a significant issue for Plans and has enormous cost and resources implications for the Form 5500 reporting disclosures that Plans will develop and provide to their ERISA customers, we ask the Agencies to explicitly confirm in the final Schedule C instructions that no indirect compensation is required to be reported on the Schedule C in the case of service providers to a welfare plan, at least until such time as the DOL amends its 408(b)(2) disclosure regulation to apply to service providers to welfare plans. We believe this clarification is consistent with the Agencies' stated goal of harmonizing the Schedule C reporting rules with DOL's existing 408(b)(2) disclosure regulation, which may be extended to welfare plans in the future, but does not currently apply to welfare plan providers.

II. Schedule J – Volume and Scope of Information Required

Issue:

The new Schedule J on group health plan information asks for a broad range of information that is burdensome and expensive to gather and report. Group health plans will necessarily reach out to their insurers and, in the context of self-insured plans, third party administrative providers for the information they will need to complete the Form 5500.

Recommendation:

The Agencies should prioritize the information they need and reduce the amount of information collected to ease the substantial new burdens placed on group health plan filers and their service providers.

Rationale:

Plans believe that the estimated burden in the Proposed Revisions is dramatically underestimated. Moreover, the Department's analysis of the burden does not appear to consider the costs and burdens associated with developing and upgrading information technology systems in order to gather and report the required data in the form required by the Proposed Revisions. The Department's analysis also does not take into account the fact that the data necessary to complete the Form 5500, including Schedule J, under the Proposed Revisions is not currently housed in a central location and would require much interaction between different divisions of a company, and with different service providers. For example, for insurance companies, claims information is problematic because it would require interaction between the claims division, the appeals division, the large group sector and the small group sector. Moreover, claims data, rebate and refund information, and premium delinquencies represent at least three types of information that would require three different divisions within an insurer to compile and make available. The new reporting required of group health plans on Schedule J alone will impose a huge burden on group health plans all at once when the reporting requirements go into effect.

In the context of welfare plans, the DOL is authorized to require the reporting of "such data or information [as] is necessary to carry out the purposes of [Title I of ERISA.]" ERISA § 104(a)(2)(B). We strongly urge the Agencies to carefully consider each new reporting element and prioritize those elements that they consider most important to their data gathering and enforcement goals. Those items that they determine are not absolutely necessary to meet their goals should be eliminated or delayed, so as not to impact group health plans with an overwhelming number of new reporting challenges at once.

III. Schedule J, Line 18 – Benefit Claims Processing and Payment

Issue:

The information required to be reported in benefit claims is ambiguous due to the use of undefined terms.

Recommendation:

The Agencies should incorporate the definitions related to claims from the National Association of Insurance Commissioners' ("NAIC's") Market Conduct Annual Statement.

Rationale:

Schedule J, Line 18, relating to benefit claims, contains many undefined terms, such as "claim" and "denial." Reporting that Plans are already required to make to state insurance regulators addresses this issue by defining certain terms clearly and consistently.

The NAIC recently adopted a Market Conduct Annual Statement for the Health Line of Business ("MCAS"). Pages 11-14 of the MCAS contain definitions relating to claims administration. We ask the Agencies to make clear that these definitions may be used when completing Schedule

J, Line 18 relating to benefit claims. These well-settled definitions will make it significantly easier for Plans and other health insurance issuers (and TPAs) to gather the information necessary to complete this part of Schedule J. The use of consistent definitions will also allow for uniform programming across different sectors or segments of an ASO provider or insurer's different lines of business. Consistent definitions will also aid the Agencies and researchers who will review Form 5500 data as the data will be consistent across ERISA group health plan filers.

IV. Schedule A, Line 11; Schedule J, Lines 8, 17 – Reporting Premium Delinquencies and Coverage Lapses

Issue:

Schedule A, Line 11; Schedule J, Lines 8, 17, require reporting of detailed plan-level information concerning premium payment delinquencies, including the number of times delinquent, and for each time, the number of days delinquent, and lapses in insurance coverage.

Recommendation:

This requirement to report insurance premium delinquencies and lapses in coverage should be eliminated or substantially scaled back based on the fact that the costs associated with gathering and reporting this information will greatly exceed the usefulness of this information. In addition, the Agencies should clarify that reporting related to premium delinquencies and lapses in coverage should apply only to such delinquencies and lapses at the ERISA plan level, and not where delinquencies or lapses occur with respect to individual participants covered under the ERISA plan.

Rationale:

Premium delinquencies for insurance provided through group health insurance policies may occur for a variety of reasons and are not tracked by health insurance issuers. These delinquencies may involve mistakes or good faith disputes as to amounts due or rebates and credits owed or not applied. They might also occur due to staffing changes or turnover at the employer, or for any number of other reasons that amount to inadvertent oversights or mistakes. Once resolved, issuers do not keep a record of these delinquencies and certainly do not keep records indicating the number of times and number of days delinquent for each overdue payment. Thus, this requirement would require substantial and costly systems changes to capture and track new information.

In addition to premium delinquencies at the plan level, premium delinquencies may also occur from time to time with respect to individual participants within an ERISA plan. For example, when participants take a leave of absence or otherwise suspend employment with their employer, their contributions toward insurance coverage may lapse resulting in a delinquency or lapse in coverage for an individual. The Agencies should clarify that this reporting requirement does not apply to delinquencies or lapses in coverage resulting from failures to remit contributions on account of individual covered employees.

Group health insurance policies may go out of force due to mistakes in premium payment or good faith disputes over the premium amounts due and be subsequently reinstated. Health insurance issuers do not keep records of every lapse of coverage, especially after a policy is reinstated because this information is not needed for any business purpose useful to the insurer. Again, this requirement would require new systems to be developed to capture and track new information.

The Agencies should either eliminate or scale this requirement back. For example, one form of limited reporting that could potentially be provided is that reporting could be required only if the plan-level policy is in lapse due to nonpayment of premium as of the end of the plan or policy year. The requirement to report delinquencies and lapses associated with individual participants, as opposed to plan-level lapses, should be eliminated.

V. Schedule J, Line 6 – COBRA Information

Issue:

Schedule J, Line 6 requires reporting of detailed information on coverage, including the number of persons offered COBRA coverage during the plan year, the number of persons electing COBRA coverage during the year, and the number of persons receiving COBRA coverage during the plan year.

Recommendation:

The Agencies should recognize that group health insurance issuers and third-party administrators ("TPAs") will often have little to no information on COBRA enrollees, especially for self-insured plans. The Agencies should acknowledge, with respect to COBRA information and other information required by Schedule J as specified throughout this comment, that a group health plan's insurance issuer or TPA has no obligation to provide a plan customer with information regarding the group health plan that it does not have within its ordinary business records related to the group health plan.

Rationale:

In the case of self-insured plans, group health issuers and TPAs will likely have little or no information about COBRA enrollees. This is because a self-insured employer will likely utilize a separate COBRA administrator to assist it in providing COBRA coverage and that provider should be looked to as the source of information on COBRA enrollees.

Accordingly, the Agencies should acknowledge that, for purposes of supporting the ERISA plan's Form 5500 filing, a plan's health insurance issuer and TPA may not have all of the information needed by the plan administrator to complete the Form 5500, Schedule J, including COBRA information. Moreover, the Agencies should clarify that, for purposes of the plan's completion of Schedule J, a health insurance issuer or TPA has no obligation to provide information that it would not have in its ordinary business records related to the plan customer. This acknowledgement would be consistent with the disclosure obligation of insurance

companies that issue group health insurance contracts to plans under current ERISA reporting regulations. In particular, we note that a DOL reporting regulation at 29 C.F.R. § 2520.103-5 does require an insurance company to provide certain information to the plan sponsor that the sponsor may need to complete its Form 5500.

However, this regulation clearly limits the insurer's Form 5500 disclosure obligation to only that information that is contained within the ordinary business records of the insurance company. Under the regulation, an insurer is required to provide only "such information as is contained within the ordinary business records of the insurance carrier or other organization and is needed by the plan administrator to comply with [the Form 5500 reporting requirements]." *See* 29 C.F.R. § 2520.103-5(c)(1)(i). It would be very helpful if the Agencies would clarify in the final Form 5500 revisions that (1) the obligation to file a complete and accurate Form 5500 falls on the plan administrator and not the plan's service providers, and (2) for purposes of Schedule J, insurers and TPAs do not have an obligation to provide information to a plan sponsor that is beyond the scope of their ordinary business records related to the plan customer.

VI. Schedule C, line 1a – Identification of Contact Information for Service Providers

Issue:

Schedule C, line 1a requires the plan administrator to include the name and address of a contact person for each service provider that is reported on Schedule C and is not an individual.

Recommendation:

The Agencies should eliminate the requirement to provide contact information, including a name and address, for each service provider because this information will not provide useful information to the constituencies that review the Form 5500 and should not appear in a public document.

Rationale:

The Form 5500 is a public document, available through the DOL website to any member of the public, and subject to review by the Agencies, plan participants and beneficiaries, and researchers. We respectfully ask the Agencies to remove the requirement to report a contact person, including address, for each service provider. This contact information should not be presented on the Form 5500 for a number of reasons. First, a contact person at a service provider will not be authorized to communicate with federal agencies, research groups, or plan participants and beneficiaries who might seek to contact it from information provided on the Form 5500. Therefore, any inclusion of this information on the Form 5500 cannot serve any useful purpose, and will only complicate the process of completing the Form unnecessarily. Based on the Agencies' Proposed Revisions, contact information will appear on the Form 5500 for the plan sponsor, the plan administrator, the named fiduciary and the plan's trustee. To the extent that the Agencies, plan participants or researchers have questions or concerns about the plan's services arrangements, these concerns should be directed to one of these parties, each of whom may have broad fiduciary responsibility for the administration and/or assets of the plan. The plan sponsor will already have each service provider's contact information through its

ordinary interaction with the provider and will have no need to use the Form 5500, a public document, as the repository of this information.

VII. Schedule C, Line 1d – Identification of Service Provider as a Fiduciary

Issue:

Schedule C, Line 1d requires a service provider to be identified as an ERISA fiduciary if they were a fiduciary at any time during the plan year.

Recommendation:

The Agencies should make clear that the "yes" or "no" fiduciary identification box on Schedule C is required only for covered service providers within the meaning of the ERISA section 408(b)(2) disclosure regulation. Alternatively, the "yes" or "no" fiduciary identification box should be expanded to allow the plan administrator to make it clear when the service provider serves as an ERISA fiduciary for limited purposes, such as in the case of a TPA or insurance issuer that may provide claims decision-making services in addition to other administrative services that would not cause it to be a fiduciary.

Rationale:

The proposed changes to Schedule C include a "yes" or "no" checkbox that requires the plan administrator to indicate whether a service provider was an ERISA fiduciary at any time during the plan year. This box is particularly problematic in the case of providers to group welfare plans. Many welfare plan providers have limited fiduciary roles with respect to the plan, and because the answer is limited to "yes" or "no," the question could lead the plan's fiduciary, plan participants, beneficiaries, researchers and the Agencies to believe that the provider acknowledges fiduciary status for all services it provides. For example, health insurance issuers and TPAs commonly have carefully negotiated services agreements under which they may accept ERISA fiduciary status only for certain limited purposes (such as for claims decision-making) but not for other services that they provide, such as recordkeeping, eligibility processing, Form 5500 preparation, and distribution of disclosures. In other cases, although health insurance issuers and TPAs are involved in making initial claims decisions, they may disclaim fiduciary status based on a theory that they are merely following detailed policies and procedures established by the plan sponsor, and they exercise no discretion. In many cases whether issuers and TPAs acknowledge fiduciary status in connection with claims decisions turns more on contract negotiations than the substantive services provided; and a single group health plan may have some issuers that acknowledge fiduciary status and others that disclaim it for essentially the same services.

We support the Agencies' objective to harmonize the Schedule C reporting rules with the DOL's 408(b)(2) regulation. Consistent with this goal, we recommend that the Agencies require the fiduciary identification box only in the case of covered service providers within the meaning of the ERISA section 408(b)(2) regulation. In this regard, covered service providers are required to specifically acknowledge their fiduciary status under ERISA section 408(b)(2), so plan administrators will have a disclosure on which to base their Schedule C response, and certainty

in completing the line. *See* 29 C.F.R. § 2550.408b-2(c)(1)(iv)(B). Later, when the DOL promulgates a final 408(b)(2) disclosure rule for welfare plans, it could expand this Schedule C line to welfare plan providers at that time as appropriate.

As an alternative, we recommend that this line be expanded to allow the plan administrator to identify those providers who may act as a fiduciary for a limited range of services but not for all services that they provide. For example, we would recommend adding a third box to the question that would be labeled "check this box to indicate a provider that acknowledges fiduciary status for some but not all services provided." Such a box would allow the filing to be more informative as to the scope of the provider's fiduciary status and be more reflective of the complex services arrangements that plans have today with their fiduciary providers.

VIII. Schedule J, Line 7 – Rebates, Reimbursements, Refunds

Issue:

Schedule J, Line 7, requires detailed reporting of rebates, reimbursements, or refunds not reported under Schedule A.

Recommendation:

The Agencies should not require detailed reporting with respect to rebates – including the amount and date of each individual rebate, and how the rebate was utilized – particularly in the case of pharmaceutical rebates. The question regarding rebates and refunds should be eliminated in its entirety, or reduced to a simple "yes" or "no" question asking whether any rebate or refund was received by the plan sponsor. Moreover, a payer of a refund or rebate will have no knowledge in most cases of how a rebate or refund was utilized. Therefore, the final Form 5500 revisions should be clear that, for purposes of Schedule J, a group health insurance issuer is not obligated to furnish information that it does not have in its ordinary business records related to the customer. Finally, with respect to rebates and refunds, the final Form revisions should make clear that the plan administrator may report rebates and refunds either in the plan year that they are accrued, or paid, as long as it does so consistently.

Rationale:

Schedule J, Line 7, requires reporting of rebates, reimbursements, or refunds from service providers "…other than those reported on Schedule A…." This line requires detailed information about each individual rebate or refund, including the amount and date received of each rebate, as well as how the rebate was used or allocated.

There are several problems with this reporting requirement. First, in the case of pharmaceutical rebates received by plans, these rebates are typically subject to highly specific contractual provisions negotiated by the plan sponsor and the plan's pharmacy benefit manager ("PBM"). These contractual provisions establish the amount of rebates that the plan will receive as well as the timing with which the rebates will be paid, often calculated on an annual (or other periodic) basis. For example, a typical rebate provision could provide that the plan and PBM will share the pharmaceutical rebates earned by the plan's PBM according to stated percentages

(*e.g.,* the plan and PBM share the rebates in a 50/50 split). In other cases the plan and the PBM may agree that the plan is entitled to a stated dollar amount of each rebate earned by the PBM, but the PBM will keep the balance of any rebates earned, or vice-versa (*e.g.,* the plan is entitled to the first $0.50 of each pharmaceutical rebate earned by the PBM and the PBM keeps the balance). Sometimes earned rebates are paid in the aggregate to the plan periodically throughout the plan year, and in other cases rebates may be held by the PBM, or advanced to the plan, subject to a reconciliation is performed at the end of the year (or at other periods). Also, sometimes the plan and PBM agree to use the rebates that are owed to the plan to offset the administrative fees due to the PBM if they are unpaid within certain timeframes. With these highly customized contractual terms that govern the payment of pharmaceutical rebates, achieving the detailed plan-level reporting of each and every rebate will be a practical impossibility in most cases.

With respect to pharmaceutical rebates in particular, we also note that the DOL has issued specific reporting relief that generally relieves ERISA plans of the obligation to report pharmaceutical rebates received by PBMs as indirect compensation on Schedule C. *See* Supplemental Frequently Asked Questions About the 2009 Form 5500, Q27. Requiring specific plan-level reporting of pharmaceutical rebates on Schedule J would essentially eliminate DOL's existing Schedule C reporting relief, and would require ERISA plans and providers to gather information on which the DOL specifically chose not to require reporting. We believe that if the DOL intends to require service providers to gather and report this information to their ERISA covered customers, the DOL should specifically promulgate a regulation under ERISA section 408(b)(2) that applies to welfare plan service providers through notice and comment rulemaking that would review this issue more thoroughly.

An additional issue is that the TPA, PBM, or other rebate payer in most cases will have no knowledge of how the rebate or refund was utilized by the plan sponsor, whether it was returned to participants, used for a premium holiday, or otherwise. In this regard, the DOL has made clear that the decision as to how to utilize a rebate paid to the sponsor that is an asset of the plan is a fiduciary decision to be made by the plan sponsor subject to ERISA's fiduciary standards of conduct. DOL Technical Release 2011-04 (Dec. 2, 2011). Again, the final Form revisions should acknowledge that a group health plan's service provider, whether an issuer or TPA, is required to provide the plan sponsor with only that information that the provider has within its ordinary business records, but not information about plan sponsor decisions that it does not have.

Finally, rebates and refunds may be earned based on plan activity (such as claims experience or pharmaceuticals purchased) that occurs during a plan year but are actually paid out later after the plan year. It would be helpful if the Agencies clarified that a rebate may be reported during the plan year in which it is earned, or the plan year in which the rebate is actually paid, in the discretion of the plan sponsor.

We strongly urge the Agencies to eliminate question 7 in its entirety. As an alternative, the question could be structured as a simple "yes" or "no" question, asking only whether the plan sponsor received any rebate, refund or reimbursement during the year other than reflected on Schedule A. The Agencies would be free to raise additional questions regarding the amount and timing of rebates received with the plan sponsor on further review outside the Form 5500 process.

IX. Schedule J, Lines 4a(1)(c), 16 – Employer/Employee Contributions

Issue:

Schedule J, Lines 4a(1)(c), 4a(2), and 4a(3) require the plan administrator to indicate whether premium payments, contributions for benefits, and contributions made to a trust come from the employer and/or from participants. In addition, line 16 requires the reporting of specific amounts of employer and employee contribution levels, both contributions received and receivable.

Recommendation:

It should be acknowledged that in most cases health insurance issuers and TPAs will not know whether contributions for premiums or for self-insured benefits come from participants or the employer, and will not be able to provide the employer with a breakdown of the amount of employer versus employee contributions received, either in the insured group health plan or in the self-insured context. We recommend that the Agencies make clear that for purposes of Schedule J, a group health insurance issuer has no obligation to provide information to support the plan administrator's Form 5500 filing that is not within the issuer's ordinary business records related to the customer.

Rationale:

The levels of contribution between employers and employees are almost always known solely to the employer sponsoring a group health plan and would not generally be known to insurers and TPAs. Issuers and TPAs merely receive aggregate payments from the group health plan for the premium or contribution obligation due and have no information on the how the employer allocates those contributions between the employer and employees. Therefore, issuers and TPAs will be unable to assist in providing this information to their plan customers for purposes of completing the Form 5500.

In addition, the Agencies should clarify that the term "premiums" refers to payments made for a health insurance policy. Black's Law Dictionary 1371 (10th ed. 2014). Accordingly, if premiums are paid to an insurance company for benefits provided under the plan through an insurance contract, lines 4(a)(1) apply. If plan benefits are not provided through the purchase of an insurance contract, lines 4(a)(1) would not apply.

X. "Prototype" or "Off-the-Shelf" Insurance Products

Issue:

Schedule J, Line 4a(1)(b) requires entry of the "identification number" of "prototype" or "off-the-shelf" insurance products funding a group health plan.

Recommendation:

It should be clarified that references to "prototype" or "off-the-shelf" insurance products refer to insurance products that have been approved by state insurance regulators regardless of whether those products permit certain terms of the contract to be changed. Moreover, these identifying numbers should be made optional.

Rationale:

"Prototype" or "off-the-shelf" insurance products are not terms that are known or readily understood in the business of group health insurance. The Form 5500 and its instructions should define these terms or explain what the Agencies intend in order to clarify how to answer this question.

These terms appear to be a reference to the fact that as a general rule, insurance policy forms must be approved by state insurance regulators before they may be used and sold in a state. However, it must be noted that state laws vary and that there are situations where a group health insurance policy must only be approved in the domiciliary state of a group policyholder and need not be approved by other states in which an employer may have employees. Further, even when approved, some group health insurance products may permit certain terms to be agreed upon by a health insurance issuer and an employer that is a group policyholder, and this term will not be specified in the policy form as approved by a state insurance regulator.

Also, it is not clear what is meant by the "identification number" for the product. The preamble to the Proposed Revisions indicates that this number is something "…such as a state assigned policy identification number)…." 81 Fed. Reg. at 47558. Issuers assign form numbers to products filed with state insurance regulators for approval, and state insurance regulators may assign tracking numbers to form filings, either on their own or through the System for Electronic Rate and Form Filing ("SERFF") used by states to approve rate and form filings. The Departments should clarify whether they mean numbers assigned by states or through SERFF (or both).

There may be situations in which a product need not be approved by state insurance regulators. For example, a contract for administrative services that does not involve transfer of risk is not considered an insurance product and is not subject to review and approval by state insurance regulators. The instructions for Form 5500 should make it clear that information on "prototype" or "off-the-shelf" products may be provided as optional information but is not required.

XI. Schedule A, Line 7 – Number of Covered Persons

Issue:

Line 7 of Schedule A has been modified so as to make clear that plan administrators are required to provide the approximate number of persons covered under each benefit type, including participants, beneficiaries, and dependents.

Recommendation:

The requirement to report the number of covered persons, including beneficiaries and dependents, should be eliminated. For purposes of line 7 of Schedule A, it should be permissible to report only the number of covered participants, without regard to beneficiaries and dependents who may also receive coverage by reason of the covered participant.

Rationale:

Plan sponsors rely on their insurers to provide them with the information they need in order to complete Schedule A. However, insurers currently pull data related to the information provided for purposes of Schedule A that does not include the number of beneficiaries and dependents covered under group health plans. In our experience, for purposes of Schedule A's current line 1(e), most insurers currently provide the number of "subscribers" or "contract holders" which provides only the number of covered employees under the insurance policy, but does not include beneficiaries and dependents. Most insurers would have to modify their current data systems, or pull data from a different system entirely, in order to provide information that would include beneficiaries and dependents. We believe that the costs associated with systems changes needed to provide this data would outweigh the benefits of the information and would be passed directly on to insured plan customers. For this reason, we ask the Agencies to clarify that reporting that is limited to the number of employees or participants covered under the insurance policy, without including beneficiaries and dependents, is sufficient for purposes of line 7 of Schedule A. We also note that the participant count lines on the main Form 5500 for both welfare and pension plans (current lines 5 and 6 on the Form 5500) generally take into account only covered employees and not dependents or beneficiaries. There is no reason that the "covered persons" line of Schedule A should count a more broad range of individuals than the participant counts set forth on the main Form 5500.

XII. Schedule J, Line 5 – Benefit Design

Issue:

Schedule J, Line 5, asks for information on various benefit package options to the plan (including grandfathered status under the ACA, a high deductible health plan, an HRA, or an FSA).

Recommendation:

It should be recognized that health insurance issuers will not be aware of each of the features identified by line 5 for many of their plan customers. The Agencies should acknowledge in writing that issuers and TPAs with respect to group health plans have no obligation to provide information to the plan sponsor that is not within the provider's ordinary business records related to the customer.

Rationale:

Schedule J, Line 5, asks whether a group health plan contains benefit packages that include features such as grandfathered status under the Affordable Care Act, a high deductible health plan, health reimbursement arrangements, or flexible spending accounts.

An issuer or TPA is unlikely to know whether any of these benefits are offered by its ERISA group health plan customers. Such a provider will be familiar with only those parts of the group health plan for which it issued group health insurance policies or for which it has administrative duties. Therefore, it should be recognized that health insurance issuers will not necessarily have all of this information to provide to their customers. Again, we ask that the Agencies acknowledge in writing that group health issuers and TPAs with respect to group health plans are required to provide only that information that is contained within their ordinary business records to their plan sponsor customers.

XIII. Preamble and Instructions (81 Fed. Reg. 47556-4557, 47560; *see* 29 C.F.R. § 2520.104–21) – Elimination of Current Exemption from Filing for Small, Fully Insured Group Health Plans

Issue:

The Proposed Revisions eliminate the current reporting exemption from Form 5500 filing for small (less than 100 participants), fully insured group health plans and require a limited Form 5500/Schedule J filing for these plans.

Recommendation:

The Agencies should recognize the burden this new filing requirement for small, insured plans places on health insurance issuers and TPAs and that these costs will be transmitted directly to customers. Moreover, to mitigate the impact of these changes, the Agencies should retain the current reporting exemption for small unfunded or fully insured plans that provide solely excepted benefits within the meaning of ERISA section 733(c).

Rationale:

Under the Proposed Revisions, small, fully insured group health plans will be subject to a Form 5500 filing obligation for the first time. Most of these small plan sponsors will turn to their health insurance issuers and TPAs for assistance in completing the Form, because employers that maintain these plans will lack the expertise and time to complete the report. Small employers

have limited resources better directed to growing their businesses and not on completing reports required by the federal government. They will doubtlessly ask their health insurance issuers to complete the Form 5500 for them as an additional service.

The estimated burden for completion of the Form does not clearly indicate that the Agencies took into account the additional burden in the form of time, resources and systems development that will be placed on health insurance issuers and TPAs so that they can assist small employers in completing and filing Form 5500. Also, as described in our comments V, VIII, IX, and XII there is information that is requested on the Schedule J lines that apply to small, fully insured plans that insurers and TPAs will not have. As a result, these entities will have to develop new procedures and systems, and will have to interact with plan sponsors (such as through a questionnaire or otherwise) in order to gather the information required for those lines. These costs will be passed directly along to the small plans that will require these new reports. The Agencies should review the estimated burden and include the costs to health insurance issuers and TPAs to use their time and resources to provide services to small employers that are now required to File Form 5500.

Particularly in the case of limited scope dental insurers, limited scope vision insurers, and providers of other limited scope health insurance contracts, these providers will face tremendous challenges and costs in order to develop the systems necessary to provide Form 5500 data to their plan customers. And, in our experience, issuers that issue these limited scope insurance contracts provide them through a completely separate division of the insurance company from other group health insurance coverages that may have limited capabilities with respect to Form 5500 assistance. To limit the impact of the elimination of the reporting exemption for small welfare plans, we ask that the reporting exemption for small, fully insured welfare plans be retained for those plans that provide only excepted benefits within the meaning of ERISA section 733(c). We believe that retaining the Form 5500 reporting exemption for small welfare plans for excepted benefits makes sense because these benefits have been specifically carved out of the coverage and other benefit mandates that are set forth in ERISA part 7. We recommend that those ERISA-covered plans that provide solely excepted benefits within the meaning of section 733(c) should remain eligible for the reporting exception for small fully insured or unfunded welfare plans, provided the conditions of the reporting exemption are met.

XIV. Schedule J – Application to Plans that Provide Excepted Benefits

Issue:

The Proposed Revisions specifically provide that Schedule J must be completed by ERISA plans that provide solely "excepted benefits" within the meaning of ERISA section 733(c). *See* 81 Fed. Reg. at 47634-35.

Recommendation:

The Agencies should exempt ERISA-covered plans that solely provide "excepted benefits" within the meaning of ERISA section 733(c) from the requirement to complete a Schedule J.

Rationale:

Under part 7 of ERISA, an ERISA-covered plan that provides solely "excepted benefits" within the meaning of ERISA section 733(c) is exempt from the coverage and other benefit mandates rules set forth in part 7 of ERISA. Because these plans are not treated similarly to "group health plans" for purposes of part 7 of ERISA, these plans should not be subject to the detailed reporting requirements of Schedule J. While it may make sense for these plans to be subject to a requirement to file the main Form 5500, as well as Schedule A to reflect insurance contracts used to provide benefits, we believe the costs associated with requiring these plans to complete Schedule J will greatly outweigh the usefulness of the information gathered and reported. Moreover, excepting these limited scope plans from Schedule J is more consistent with how these benefits are treated differently from group health plans under part 7. Accordingly, we strongly urge the Agencies to exempt plans that provide solely excepted benefits within the meaning of ERISA section 733(c) from the requirement to file a Schedule J. Assuming that the Agencies accept both of our comments XIII. and XIV, small plans that provide solely excepted benefits could be exempt from Form 5500 reporting if fully insured (and the conditions of 29 C.F.R. § 2520.104-20 are met), while large plans that provide solely excepted benefits would be subject to Form 5500 reporting generally, but not Schedule J.

XV. Instructions (81 Fed. Reg. 47602) – Extension of Time to File

Issue:

Under current Form 5500 reporting rules, a plan's Form 5500 is due on the last day of the seventh month after the plan year ends. A one-time, automatic extension of time for filing is available by filing the Form 5558, which allows the plan an additional two and a half months to file the Form 5500. The Agencies should grant an additional extension of time to file the Form 5500 for all plans during the initial years that the revised Form 5500s are due.

Recommendation:

The Agencies should grant an additional extension of time to file the Form 5500 for all plans during the initial years that the revised Form 5500s are due. Alternatively, the Agencies should adopt a non-enforcement policy with respect to the imposition of civil penalties under ERISA

section 502(c)(2) in the case of late Form 5500 filings for the first several years after the revised Form 5500s are in effect.

Rationale:

Filers are entitled to a one-time extension of time to file Form 5500 of up to 2½ months by filing Form 5558. The Agencies have exercised their discretion to grant additional extensions for other reasons (*e.g.,* additional extensions of time were granted in recent years for filers affected by hurricane Katrina). The Form 5500 changes proposed by the Agencies are sweeping in scope, and will require plan administrators to expend substantially more resources and time to compile and report the additional information. As explained above, service providers will be required to develop complex new systems to compile and provide the new information to their ERISA plan customers. Plan administrators will rely heavily on their service providers for assistance in gathering and compiling the new information to complete the revised forms and schedules. Further, the Proposed Revisions will require additional interpretation and guidance from the Agencies that will likely require additional systems changes once the final Form changes are released.

For these reasons, the BCBSA urges the Agencies to make available a generous additional extension of time to file the Form 5500 in the first several years that the final Form revisions are in effect in light of the extensive additional information that will be required to be reported going forward. During this period at least six-month extensions of time should be available.

As an alternative, the Agencies should adopt a non-enforcement policy with respect to the imposition of civil penalties under ERISA section 502(c)(2) for late Form 5500 filings for the first several years that the revised Form 5500s are in effect. This relief is especially critical because the DOL has recently nearly doubled the maximum civil penalties that may be imposed in the case of late or deficient filings under ERISA section 502(c)(2). *See* 81 Fed. Reg. 43430, 43454 (Jul. 1, 2016) (Maximum civil penalty for late or deficient Form 5500 filings is increased to $2,063 per day for civil penalties assessed after August 1, 2016).

XVI. Applicability Date

Issue:

A DOL news release states that the form revisions would be implemented beginning with the plan year 2019 Form 5500 series returns/reports, but a DOL fact sheet also indicates that some form changes may be made earlier or later, depending on the public comments and developments in the procurement process for the electronic filing system used by the Agencies.

Recommendation:

Adequate time for implementation of the Proposed Revision should be given before they are made applicable to employee benefit plans. BCBSA suggests that all of the Proposed Revisions should be applicable to filings in the same plan year, rather than in various plan years. Moreover, the Agencies should allow filers at least two full years to develop the systems

necessary to capture and report the new information. Therefore, if the final Form revisions are issued in 2017, we would ask for the revisions to be effective for plan years beginning on or after January 1, 2019. If the final Form revisions are not issued until sometime in 2018, we ask that the revisions be made effective for plan years beginning on or after January 1, 2020 (and so forth).

Rationale:

Adequate time for systems changes is necessary, especially in light of substantial systems changes needed to capture information not previously required to be reported and (as noted above) preparation must be made in order to assist small employers in responding to a new filing requirement. We urge the Agencies to give filers at least two full years to implement the final Form revisions, regardless of when the final Form revisions are issued. We strongly believe that at least two years is needed to develop the systems and procedures that will be necessary to comply with these new requirements and to provide our plan sponsor customers with the assistance they will require to comply with these new requirements.

XVII. NAIC Company Code, National Producer Number, "National Insurance Product Registry Number"

Issue:

The Proposed Revisions do not use the terms NAIC Company Code, National Producer Number, "National Insurance Product Registry Number" properly.

Recommendation:

The final Form revisions should be revised so that these terms are used correctly and consistently.

Rationale:

NAIC Company Code

The NAIC Company Code is a unique identifier assigned by the NAIC only to risk-bearing entities to track their reporting to the NAIC in accordance with state laws. Insurance agencies and other non-risk bearing entities are not assigned NAIC Company Codes. The proposed revision to Schedule A, Insurance Information, Line 1c, proposes to clarify that the "NAIC Code" sought is the "NAIC Company Code." 81 Fed. Reg. 47576. This is an appropriate revision.

National Producer Number

"The National Producer Number ('NPN') is a unique NAIC identifier assigned through the licensing application process or the NAIC reporting systems to individuals and business entities (including, but not limited to producers, adjusters, and navigators) engaged in insurance related activities regulated by a state insurance department. The NPN is used to track those individuals and business entities on a national basis." The Proposed Revisions ask for the NPN

in several places, especially in Part II of Schedule J, Service Provider Information for group health plans. 81 Fed. Reg. 47558, 47587, 47635.

In Schedule J, Part II, some of the functions of the service providers listed may be carried out by health insurance issuers that do not have a National Producer Number.

In addition, some states may not report all of their licensees to the NAIC's Producer Database or may not require licensing for a particular activity, in which case persons performing those functions will not have licenses or NPNs.

Also, Line 15c of Schedule C asks for the National Producer Number for a stop-loss insurer instead the NAIC Company Code.

The agencies should confirm that the instructions require entry of a National Producer Number on an optional basis, only if it is available to the person performing the service for the group health plan.

Also, the Agencies should clarify that a stop-loss insurer should provide an NAIC Company Code, not a National Producer Number (Schedule J, Line 9c).

"National Insurance Product Registry Number"

This does not seem to be an actual term used by any NAIC affiliates. The Departments should review whether the National Producer Number or NAIC Company Code is intended here, and provide appropriate descriptions in the instructions, as recommended above, on the use of these data items.

XVIII. Schedule J, Line 23, SPD, SMM, SBC

Issue:

The Proposed Revisions require the plan administrator to attest to whether or not the plan's summary plan description ("SPD"), including any summaries of material modification ("SMMs"), and summary of benefits and coverage ("SBC") are in compliance with applicable legal content rules.

Recommendation:

The Agencies should recognize that health insurance issuers and TPAs will not be aware of any features of the plan subject to disclosure under the SPD, SMM and SBC rules that are outside the scope of their services to the plan. Therefore, the Agencies should acknowledge in writing that to the extent that plan administrators rely on information provided by issuers and TPAs in order to complete this line, issuers and TPAs cannot comment on features of the plan that are not within the provider's ordinary business records related to the customer. Moreover, the reference to the summary annual report ("SAR") in the instructions should be deleted because proposed line 23 itself contains no reference to the SAR, and should not refer to the SAR.

Rationale:

In many cases plan sponsors may rely on insurance issuers and/or TPAs to develop model SPDs, SMMs and SBCs for various benefit options offered under a group health plan. Nonetheless, issuers and TPAs would be responsible only for generating SPD, SMM and SBC content for the benefit options that they insure or administer. In many cases, issuers and TPAs may provide initial draft SPDs and SMMs subject to further review and approval by the plan administrator. These insurers and TPAs cannot be responsible for any attestation as to the compliance of the SPD, SMM and SBC for the entire group health plan as a whole, which may have other benefits and features beyond the scope of disclosures developed by the issuer or TPA for its client. In this regard, particularly in the case of large group health plans, a plan may offer many different coverage options and benefit offerings that are offered by several different insurers and providers. However, as a practical matter, because many plan sponsors will seek assistance in completing the Form 5500 from their issuers and TPA providers, they will doubtlessly look to these providers to assist them in responding to line 23. As we stated in comments V, VIII, IX and XII, it would be very helpful if the Agencies would clarify that the obligation to complete the Form 5500, and Schedule J, falls on the plan administrator, and that issuers and TPAs are not required to provide information, including compliance attestations, to the plan administrator with respect to completing the Form 5500 that relates to plan features outside the scope of their services to the ERISA customer.

We also note that the instructions to line 23 refer to the SAR in addition to the SPD, SMM and SBC. Proposed line 23 currently does not, and should not, refer to the SAR. The SAR is a summary of the content of the Form 5500, due to be distributed to participants subsequent to the filing date of the Form 5500. The Form 5500 could not reasonably contain an attestation as to the content of a disclosure that has not been distributed prior to the date the Form 5500 is filed. For this reason, the reference to the SAR in the instructions should be deleted as inappropriate.

XIX. Schedule J, Lines 24-30, Compliance with HIPAA, GINA, MHPAEA, Etc.

Issue:

The Proposed Revisions require filers to state whether coverage provided by the plan is in compliance with HIPAA, GINA, MHPAEA, the Newborns' and Mothers' Health Protection Act of 1996, the Women's Health and Cancer Rights Act of 1998, Michelle's Law, and the Affordable Care Act.

Recommendation:

It should be recognized that health insurance issuers will not be aware of a plan's compliance with all of the requirements of the statutes referenced in the Proposed Revisions. Further, the Agencies should clarify that the questions are seeking information on good faith compliance, so that it is clear that Form 5500 civil penalties will not apply in the event that the Agencies take a different position on the plan's compliance status and disagree with the answers reported on Schedule J, Lines 24-30.

Rationale:

Under the Proposed Revisions, filers must answer whether the plan to which the Form 5500 relates is compliant with, *inter alia*, the Affordable Care Act. Many plan sponsors rely on their insurance issuers for the structuring of particular benefit offerings. As such, plan sponsors may turn to issuers, in their capacity as insurers and ASO providers, for information regarding compliance with certain aspects of the Affordable Care Act, such as essential health benefits, annual and lifetime dollar limits, and prescription drug coverage. However, the question in Schedule J seems to relate to compliance with the Affordable Care Act generally, including compliance with the employer mandate. To the extent that a plan sponsor asks an issuer for an opinion or attestation regarding compliance with the Affordable Care Act, an issuer will not be able to provide a complete and accurate answer because it does not hold all information relevant to the answer as part of its business records.

BlueCross BlueShield Association

An Association of Independent Blue Cross and Blue Shield Plans

December 5, 2016

The Honorable Phyllis C. Borzi
Assistant Secretary of Labor
Office of Regulations and Interpretations
Employee Benefits Security Administration
Attn: RIN 1210–AB63
Annual Reporting and Disclosure
Room N–5655
U.S. Department of Labor
200 Constitution Avenue, N.W.
Washington, DC 20210

Submitted via regulations.gov

RE: Proposed Revision of Annual Information Return/Reports (Form 5500) RIN 1210–AB63: Response Focusing on Specific Solicitation for Comments on *Gobeille*

Dear Secretary Borzi:

The Blue Cross Blue Shield Association ("BCBSA") appreciates the opportunity to provide comments to the Department of Labor ("DOL"), as well as the Department of the Treasury and the Pension Benefit Guaranty Corporation (collectively, the "Agencies") on the specific solicitation for comments in the Proposed Revision of Annual Information Return/Reports (Form 5500) ("Proposed Revisions"), on "the proposed annual reporting requirements for plans that provide group health benefits, including the new Schedule J, in light of the Supreme Court's recent decision in *Gobeille v. Liberty Mutual Insurance Co.*" (81 Fed. Reg. 47534.)

BCBSA is a national federation of 36 independent, community-based, and locally operated Blue Cross and Blue Shield Plans ("Plans") that collectively provide health care coverage for more than 106 million – one in three – Americans. Blue Cross and Blue Shield Plans offer coverage in every market and every ZIP Code in America. Plans also partner with the Government in Medicare, Medicaid, the Children's Health Insurance Program, and the Federal Employees Health Benefits Program.

The *Gobeille* decision held that ERISA preempts Vermont's all payer claims database ("APCD") law, and therefore generally preempts APCD laws around the country. APCDs typically require that payers – including private health plans, prescription drug plans, and self-funded employer plans – submit enrollee-level claims, enrollment, and pharmacy data on a monthly or quarterly basis to a state-run centralized data repository. APCD partisans have argued that *Gobeille* dealt a substantial blow to state APCDs.

The enrollee-level, patient-specific information in APCDs is not currently collected via the Form 5500, which aggregates group data for employer sponsored ERISA plans, nor is such information proposed to be collected via the proposed Schedule J. Nonetheless, DOL is specifically seeking public comments in this Notice on the proposed annual reporting requirements for plans that provide group health benefits, including the new Schedule J, in light *Gobeille.*

At issue, therefore, is whether DOL should use the Form 5500 to collect typical APCD data, and in so doing help states overcome *Gobeille's* effect on APCDs.

We believe the answer is no: we strongly urge that DOL not promulgate any provisions related to APCDs or the *Gobeille* decision in the Form 5500 revisions. Our recommendation is based on serious legal and policy concerns.

Promulgating APCD-related provisions would be legally problematic because:

- It would be inconsistent with the settled requirements of the Administrative Procedures Act (APA) because an APCD would require a significant amount of enrollee-level, patient specific information that is not currently set forth in the Proposed Revisions.

- It would exceed authority under ERISA 104 because much of the information included in an APCD would be beyond the scope of the purposes of Title I, which requires that sponsors of private employee benefit plans provide participants and beneficiaries with adequate financial and other information regarding their plans.

- It would circumvent the tri-agency regulatory process and the specific provisions of the Public Health Service Act ("PHSA"), which may provide for some new form of national data reporting.

Promulgating APCD-related provisions would be contrary to good public policy because:

- It would impose significant administrative burden and cost on the government and private payers to collect, standardize, validate, cleanse, integrate, and secure data from multiple group health plans. For example, in 2014 California estimated that requiring the University of CA to establish an APCD would cost the state nearly $30 million – and other estimates show that private insurance carriers would need to send even more.

- It would be difficult to ensure the integrity of the data because the deep understanding of the data – and, thus, the ability to address data anomalies and inconsistencies – is found among the data holders, not by those who maintain the central repository.

- The uses (if any) to which current state APCDs are put do not relate to ERISA's purposes. The seven or so states with fully-functioning APCDs that have actively used them have generated analyses that are, for example subject to bias; often focused on

public health issues; and not integral to improving cost and quality for health plan participants and beneficiaries.

- It would put sensitive, proprietary data such as privately contractually negotiated discounts between payer and providers at risk.

- The Government can, as it already does in other programs, use distributed data approaches as an alternative to centralized data repositories, which would outweigh the practical utility of relying on APCDs.

We offer details on the legal and public policy issues below in support of our recommendation.

Further, we are submitting today a separate letter focusing on numerous other aspects of the Proposed Revisions.

We appreciate the opportunity to provide comments regarding the Proposed Revisions and the impact of the *Gobeille* case and look forward to continuing to work with the Agencies as they issue guidance on implementing revised employee benefit reporting. If you have any questions, please contact Joel Slackman at Joel.Slackman@bcbsa.com or 202.626.8614.

Sincerely,

Kris Haltmeyer
Vice President
Health Policy Analysis
Blue Cross Blue Shield Association

* * *

BCBSA DETAILED COMMENTS ON PROPOSED REVISION OF ANNUAL INFORMATION RETURN/REPORTS (FORM 5500) IN LIGHT OF *GOBEILLE*

I. Background

The Department of Labor ("DOL") and coordinating agencies' Proposed Revisions introduce a new schedule to be submitted as part of Form 5500 filings submitted by group health plans. This new schedule, the Schedule J, requires, *inter alia*, that the following questions be answered by group health plans:

1. Enter the number of post service benefit claims submitted during the plan year. How many of those claims were approved during the plan year? How many were denied? How many were pending at year-end?

2. Enter the number of post-service benefit claim denials appealed during the plan year. How many of those appeals were upheld during the plan year as denials? How many were overturned and approved?

3. Enter the number of pre-service benefit claims appealed during the plan year. How many were upheld during the plan year as denials? How many were approved?

4. Were there claims for benefits or appeals of adverse benefit determinations that were not adjudicated within the required timeframes? Number of claims. Number of appeals.

5. Did the plan fail to pay any claims during the plan year within one month of being approved for payment? Number of claims not paid within one month. Total amount not paid within one month. Number of claims not paid within three months or longer.

6. Total dollar amount of benefits paid pursuant to claims during the plan year.

See 81 Fed. Reg. 47534, 47587 (July 21, 2016).

APCDs

Currently, 18 states operate mandatory APCDs. These states typically require that payers – including private health plans, Medicaid, CHIP, state employee benefit programs, prescription drug plans, dental insurers, and self-funded employer plans – submit enrollee-level claims, enrollment, and pharmacy data on a monthly or quarterly basis to a state-run centralized data repository. The medical claims files include healthcare related data elements such as diagnosis codes, types of care received (procedure and pharmacy codes), the treating provider, insurance product type, and 'cost' amounts (charges, paid, member liabilities)

APCD information is thus wide-ranging, patient specific, information. This information is not currently collected at all via the Form 5500, which is aggregate group data for employer sponsored ERISA plans, nor is such information proposed to be collected via the proposed Schedule J.

Gobeille

At issue in *Gobeille* was the Vermont APCD. The Supreme Court held that ERISA preempts Vermont's APCD law, and therefore generally preempts APCD laws around the country. In dicta, the majority and concurring opinions alluded to the possibility that the DOL could implement an APCD.

- "[The Secretary of Labor] may be authorized to require ERISA plans to report data similar to that which Vermont seeks, though that question is not presented here." 136 S. Ct. at 945 (opinion of the court).

- "I would also emphasize that pre-emption does not necessarily prevent Vermont or other States from obtaining the self-insured, ERISA-based health-plan information that they need. States wishing to obtain information can ask the Federal Government for appropriate approval. As the majority points out, the 'Secretary of Labor has authority to establish additional reporting and disclosure requirements for ERISA plans." Moreover, the Secretary "is authorized to undertake research and surveys and in connection therewith to collect, compile, analyze and publish data, information, and statistics relating to employee benefit plans, including retirement, deferred compensation, and welfare plans.'" 136 S. Ct. at 950 (Breyer, J., concurring) (citations omitted).

Despite the effect of *Gobeille* on state APCDs, and the above opinions, it would not be proper on either legal or public policy grounds to use the Form 5500 revisions to collect APCD-type data.

II. Legal Concerns

Issue – APA Compliance:

Whether APCD requirements could be implemented in a manner consistent with the Administrative Procedures Act ("APA").

Recommendation:

Implementing APCD-related provisions would be inconsistent with the settled requirements of the APA.

Rationale:

The APA requires an agency to put the public on notice of a Proposed Revisions and specify the terms or substance thereof. 5 U.S.C. § 553(b) ("General notice of proposed rulemaking shall be published in the *Federal Register* . . . The notice shall include . . . (3) either the terms or substance of the proposed rule or a description of the subjects and issues involved.")

An agency must do more than merely state "that a new standard will be adopted [.]" *Horsehead Res. Dev. Co. v. Browner,* 16 F.3d 1246, 1268 (D.C. Cir. 1994). If the agency fails to provide adequate notice, the ensuing rule is invalid. *See Public Citizen, Inc. v. Mineta,* 427 F. Supp. 2d 7, 14-15 (D. D.C. 2006), *judgment amended on other grounds,* 444 F. Supp. 2d 12 (D. D.C. 2006), *judgment aff'd.,* 533 F.3d 810 (D.C. Cir. 2008).

As to the adequacy of the proposal, the agency must "describe the range of alternatives being considered with reasonable specificity. Otherwise, interested parties will not know what to comment on, and notice will not lead to better-informed agency decision-making." *Time Warner Cable Inc. v. F.C.C.,* 729 F.3d 137, 170 (2d Cir. 2013) (citations and quotations omitted). Importantly, if the plain language of the notice does not clearly express the agency's intent, "the notice provisions of the APA require that some indication of the regulatory intent that overcomes plain language must be referenced in the published notices that accompanied the rulemaking process. Otherwise, interested parties would not have the meaningful opportunity to comment on proposed regulations that the APA contemplates because they would have had no way of knowing what was actually proposed." *Safe Air for Everyone v. E.P.A.,* 488 F.3d 1088, 1097-98 (9th Cir. 2007) (citations omitted). Indeed, "[t]his right to participate in the rulemaking process can be meaningfully exercised . . . only if the public can understand proposed rules as meaning what they appear to say. . . . To protect the integrity of [the APA's required] procedures, we cannot permit an agency to rely on its unexpressed intentions to trump the ordinary import of its regulatory language." *Exportal Ltda. v. United States,* 902 F.2d 45, 50–51 (D.C. Cir. 1990) (citations and emphases omitted).

In order to ensure that agencies actually provide interested parties opportunity to comment, the courts developed the "logical outgrowth" test, which addresses whether a final rule is invalidly promulgated. If the agency failed to provide adequate notice in the proposed rule and otherwise did not give interested parties actual notice, the final rule is not a "logical outgrowth" of the proposed rule. "Given the strictures of notice-and-comment rulemaking, an agency's proposed rule and its final rule may differ only insofar as the latter is a 'logical outgrowth' of the former. The 'logical outgrowth' doctrine does not extend to a final rule that finds no roots in the agency's proposal because '[s]omething is not a logical outgrowth of nothing,' nor does it apply where interested parties would have had to 'divine [the agency's] unspoken thoughts,' because the final rule was 'surprisingly distant' from the Agency's proposal." *Environmental Integrity Project v. E.P.A.,* 425 F.3d 992, 996 (D.C. Cir. 2005) (internal citations and quotations omitted) (emphasis added).

As noted above, an APCD would require a significant amount of enrollee-level, patient specific information that is not currently set forth in the Proposed Revisions. For example, the Proposed Revisions do not state that the DOL will be collecting information in the Schedule J on diagnosis codes, types of care, facility type, member liabilities, provider information, or members' identifying information, all of which are core elements of an APCD.

The preamble to the Proposed Revisions merely states that the DOL is seeking comment on the Schedule J requirements in light of *Gobeille.* The Proposed Revisions do not specify the terms or substance of a proposed APCD or provide a range of alternatives being considered with reasonable specificity. As such, based on the Proposed Revisions, the public cannot

understand what is actually being proposed, and it does not have a meaningful opportunity to comment on particular reporting requirements for a proposed APCD.

Similarly, to the extent that the DOL seeks to implement any variation of an APCD through the final rule on the Form 5500, such final rule would not be a logical outgrowth of the Proposed Revisions. This is because the DOL failed to provide adequate notice and put interested parties on actual notice of the specific reporting APCD requirements under consideration by the DOL. A final rule implementing an APCD would be surprisingly and significantly distant from the Proposed Revisions.

Issue – Compliance with ERISA section 104:

Whether promulgation of APCD provisions would exceed authority under ERISA section 104.

Recommendation:

Including APCD provisions in the Proposed Revision would go beyond authority granted in ERISA sections 104.

Rationale:

ERISA section 104(a)(2)(B) allows the Secretary of the DOL broad authority to require any information or data from plans. However, such authority is limited to "where he finds such data or information is necessary to carry out the purposes of this subchapter [Title I] . . . ."

In relevant part, one of the purposes of Title I of ERISA is to protect ". . . the interests of participants in employee benefit plans and their beneficiaries, by requiring the disclosure and reporting to participants and beneficiaries of financial and other information with respect thereto . . . ." ERISA section 2(b).

Much of the information that would generally be required under an APCD would be beyond the scope of the purposes of ERISA Title I. Specifically, gathering identifying information regarding members, information about providers and facilities, diagnosis codes, and information about the dates of service and discharge would not further participants' interests in employee beneficiary plans. In addition, such disclosure and reporting would not be of financial or other information regarding an employee benefit plan.

In addition, the DOL has explicitly acknowledged that the purposes of APCDs and the purposes of ERISA are different. In its *amicus* brief in *Gobeille,* the DOL states, "[t]he Database Statute and ERISA serve different purposes. ERISA governs the design and administration of employee benefit plans, including vesting requirements, health-benefit mandates, fiduciary duties, and remedies for breach. Its reporting and disclosure requirements further those purposes. The Database Statute, in contrast, is designed to improve the quality, utilization, and cost of healthcare in Vermont by providing consumers, government officials, and researchers with comprehensive data about the healthcare-delivery system. Although those data are reflected in claims paid by various entities, including ERISA plans, the focus of the Vermont

statute has nothing to do with the claims payment process. That is why Vermont does not seek information on denied claims." Brief for the DOL as *Amicus Curiae,* pp. 10-11, *Gobeille v. Liberty Mutual Insurance Company,* 136 S Ct. 936 (2016).

The casual dicta in *Gobeille* does not expand ERISA's group based reporting scheme designed to provide oversight of plans to a scheme to collect exhaustive, patient specific information related to individual medical procedures.

Issue – Tri-Agency Regulatory Process:

Whether implementation of an APCD through the Form 5500 would circumvent the Tri-Agency regulatory process and the specific provisions of the PHSA that may provide for the establishment of some form of national data collection.

Recommendation:

Implementation of APCD provisions through PHSA provisions requires compliance with the Tri-Agency regulatory process.

Rationale:

PHSA sections 2715A and 2717 were enacted as part of the Affordable Care Act in 2010. Both of these provisions are incorporated into section 715(a)(1) of ERISA.

- PHSA section 2715A provides, "A group health plan and a health insurance issuer offering group or individual health insurance coverage shall comply with the provisions of section 1311(e)(3) of the Patient Protection and Affordable Care Act, except that a plan or coverage that is not offered through an Exchange shall only be required to submit the information required to the Secretary and the State insurance commissioner, and make such information available to the public." Section 1311(e)(3) of the ACA, in turn, sets forth transparency requirements, and provides that health plans must disclose, inter alia, claims payment policies and practices, financial disclosures, enrollment and disenrollment data, data on the number of denied claims, rating practice information, and cost sharing and out-of-network payment information. In addition, with respect to group health plans, ACA section 1311(e)(3) provides that the Secretary of Labor will update and harmonize HHS rules regarding the disclosure to participants described above with the standards set forth by the Secretary of HHS.

- PHSA section 2717 provides, in relevant part, "the Secretary [of Health and Human Services], in consultation with experts in health care quality and stakeholders, shall develop reporting requirements for use by a group health plan, and a health insurance issuer offering group or individual health insurance coverage, with respect to plan or coverage benefits and health care provider reimbursement structures that…improve health outcomes through the implementation of activities such as quality reporting…implement activities to prevent hospital readmissions…implement activities to improve patient safety and reduce medical errors…; and…implement wellness and

> health promotion activities." PHSA section 2717 also provides that such reports shall be submitted annually to the Secretary of Health and Human Services.

The Department of Health and Human Services ("HHS"), DOL, and the Department of Treasury (collectively, "Tri-Agencies") have not implemented PHSA sections 2715A and 2717. In the preamble to the final rule on Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers, HHS explicitly stated, "HHS intends that the reporting obligations established in this section and § 155.1040 will be aligned with the transparency reporting standards under section 2715A of the PHS Act. *HHS, together with the Departments of Labor and the Treasury, will coordinate guidance on the transparency in coverage standards*." 77 Fed. Reg. 18310, 18417 (March 27, 2012) (emphasis added).

Further, in Part XV of the FAQs about Affordable Care Act Implementation, the Tri-Agencies stated, "because section 2715A of the PHS Act simply extends the transparency provisions set forth in section 1311(e)(3) of the Affordable Care Act to group health plans and health insurance issuers offering group and individual health insurance coverage, the Departments clarify that the reporting requirements under section 2715A of the PHS Act will become applicable to group health plans and health insurance issuers offering group and individual health insurance coverage no sooner than when the reporting requirements under section 1311(e)(3) of the Affordable Care Act become applicable. *As previously stated, the Departments will coordinate regulatory guidance on the transparency in coverage standards for coverage offered inside and outside of the Marketplaces*." Q&A 4, FAQs about Affordable Care Act Implementation Part XV, U.S. DEP'T OF LABOR EMP. BENEFITS SEC. ADMIN. (Apr. 29, 2013), https://www.dol.gov/ebsa/faqs/faq-aca15.html (emphasis added).

More recently, regarding transparency reporting, the Tri Agencies stated, "The Departments intend to propose transparency reporting for non-QHP issuers and non-grandfathered group health plans in the future. The proposed reporting requirements may differ from those prescribed in the August 11, 2015[,] HHS proposal under section 1311(e)(3) of the Affordable Care Act, and will take into account differences in markets, reporting requirements already in existence for non-QHPs (including group health plans), and other relevant factors. The Departments also intend to streamline reporting under multiple reporting provisions and reduce unnecessary duplication. *The Departments intend to implement any transparency reporting requirements applicable to non-QHP issuers and non-grandfathered group health plans only after reasonable notice and comment, and after giving those issuers and plans sufficient time, following the publication of final rules, to come into compliance with those requirements*." Q&A 1, FAQs about Affordable Care Act Implementation (Part XXVIII), U.S. DEP'T OF LABOR EMP. BENEFITS SEC. ADMIN. (Aug. 11, 2015), https://www.dol.gov/ebsa/faqs/faq-aca28.html (emphasis added).

A natural reading of the PHSA provisions suggests that the Secretary of HHS would be the lead agency in implementing these requirements. But, at a minimum, these provisions must be implemented through a coordinated Tri-Agency process. *See* 64 Fed. Reg. 70164 (Dec. 15, 1999) *See, e.g.,* 78 Fed. Reg. 13406, 13419 (Feb. 27, 2013) ("[T]he HIPAA enforcement standard, as originally codified in [the PHSA]…applies to the market reform provisions of the

[PHSA] created by the Affordable Care Act.”). That process has not been followed in issuing the proposed revisions to Form 5500.

To the extent that the federal government has the authority to develop some form of claims data base, it is likely through PHSA section 2715A, and this has been widely acknowledged by advocates, legal scholars, and regulators alike. *See, e.g.,* Comments on Department of Labor Notice of Proposed Rule Making, National academy for State Health Policy (Sept. 20, 2016); DOL as *Amicus Curiae,* pp. 3-4, *Gobeille v. Liberty Mutual Insurance Company,* 136 S Ct. 936 (2016); 136 S. Ct. at 949 (Breyer, J., concurring).

Indeed, when read in context, the specific authority provided to the Tri-Agencies to implement PHSA sections 2715A and 2717 through rulemaking clearly suggests that Congress intended a separate, fully formed, notice and comment rulemaking would be not only appropriate, but required, for such a significant undertaking. Bootstrapping any kind of APCD proposal to the brief dicta in *Gobeille* and a one line solicitation for comments under a proposed Schedule J is clearly at odds with the ACA’s structure and purpose.

III. Public Policy Concerns

Issue – Significant Administrative Burden and Cost

Promulgation of any APCD requirements will involve significant administrative burden and cost.

Recommendation:

Collecting and storing data from multiple health plans in centralized data warehouses or repositories is expensive and time-consuming, the more so when data are collected quarterly or monthly. The industry’s widely decentralized and largely autonomous data collection efforts make data quality a significant challenge.

Rationale:

BCBSA’s views on these concerns are based in our extensive experience dealing with the challenges of assembling meaningful claims across multiple, independent companies. Currently, BCBSA has a nationally recognized data initiative known as Axis, which exploits an enormous cache of claims resources for analytic purposes: more than 107 million people’s worth of data, covering every zip code in the country, representing 93 percent of physicians and 96 percent of hospitals nationwide. BCBSA has relied on claims data from Blue Plans to provide insights into such issues as cost variations in knee and hip replace surgeries in markets across the U.S., the rapidly growing cost of specialty drugs, and differences in intensity of treatment between women and men 60 days following a heart attack.

Given the years of effort to achieve this ability to aggregate data in meaningful way, we are familiar with the inherent technical, security, and operational challenges, and the need for

sustained intellectual and financial capital, involved in building, operating, and maintaining multi-payer claims databases.

Integrating health plans' claims data requires:

- Extracting the appropriate data from thousands of entities, each of which is likely to have to integrate internally multiple sources of data.

- Examining and profiling the data to identify and prioritize data quality problems (*e.g.,* missing records, statistical data anomalies).

- Cleansing data to check for adherence to standards (*e.g.,* standards to quality check, uniform data definitions for semantic interoperability), internal consistency, referential integrity, adherence to value domains, and then to replace/repair incorrect data with correct data or specified defaults.

- A semantic or technical logic (which itself needs to be defined, designed, developed and tested) to ensure that the data from different source systems is combined and integrated to a standard data set based on the agreed to set of business rules. This could include standard algorithms for groupers to create derived data that is also stored within the data models.

- Challenges to integrating claims data include:

- Determining the combination of claim identifiers that uniquely identifies a claim across a series of modifications and adjustments.

- Attribution of claims to members – a particular challenge in the context of coordination of benefits, or tracking utilization or spending in value-based payment programs that use incentives that are not tied to individual claims (*e.g.,* risk arrangements with Accountable Care Organizations in which an end-of-year reconciliation process ascertains the existence and distribution of any shared savings).

- Accounting for special problems of paper claims (*e.g.,* higher proportion of missing data).

- Tracking individuals as they undergo life changes (*e.g.,* leave a job, change a name).

- Uniquely identifying providers and attributing members to providers.

- Establishing consistent data definitions.

The final point deserves especial attention. If data aggregation is to be accurate and cost-effective (*e.g.,* minimizing the need for data resubmissions), data users require consistent data rules and data definitions.

The National Academy for State Health Policy, among others, has proposed adopting a so-called "Common Data Layout" ("CDL") to reduce the burden on data reporters by standardizing the health care claim and related data that are currently collected by State APCDs. It bears noting, however, that the CDL is not officially finished, and is undergoing development by organizations that are neither recognized standard setting organizations nor representative of all stakeholders (*e.g.,* no employers).

But even if the CDL was a legitimate set of standards, merely standardizing the types of data elements to be collected would do nothing to minimize the burden associated with standardizing the data for consistency.

Ensuring Data Consistency

Many health plans have devoted considerable time and resources to rationalizing data rules and definitions for their own internal systems, so that health plans often interpret the data elements of a claim differently. For example, because there is no consistent definition of an "inpatient stay," health plans may define it as (1) an unbroken period that a patient spends as an inpatient; or (2) admission to a hospital that incurs room and board for an expected duration of 24 hours or longer; or (3) a day in which a person is confined to a bed and in which the patient stays overnight in the hospital. If one wishes to aggregate data across multiple plans for insights into issues around inpatient stays, common definitions are needed to make "apples to apples" comparisons.

The Cost of Aggregating Data Across Multiple Payers

Over the past decade, BCBSA has spent tens of millions of dollars to build and maintain its data repository. But as this spending occurs in the context of a closed system, it may be more relevant to look at the costs associated with states APCDs. Unfortunately, few estimates exist. The APCD Council reports that annual state APCD funding ranges from $350,000 (for a barebones data collection effort) to $2 million to establish the data system (for states ranging from approximately 1.3 million to 5.5 million lives). However, this grossly understates the true costs to the government.

For a more accurate estimate, in 2014 the California Assembly Committee on Appropriations estimated the fiscal effect of a comprehensive APCD: the bill (AB 1558) required that the University of CA establish a carrier claims database. Based on costs incurred by the smaller Colorado APCD, the Committee estimated that CA's APCD would incur $5 million for planning, $15 million for development and implementation, and ongoing maintenance costs of $7.5 million. In addition to this $27.5 million expenditure, the Committee estimated that costs to support other functions, including the development of a searchable public website and consumer assistance, as well as data provided for purchasers would probably exceed $1 million for development (and could vary greatly based on the sophistication and level of detail provided).

This estimate does not address the labor and technology cost that health plans would incur to operate, maintain, and support ongoing data submissions. We do not have an estimate of

submitting enrollee-level, patient-specific data via Schedule J. However, a report by Hewlett Packard helps to put the costs in perspective: HP estimated that for a centralized database comprising all claims in the individual and small group market, O&M costs for all of the health plans submitting data would be about 4.5 times higher than the O&M cost to the government entity establishing the APCD (*i.e.,* if CA would need to spend $7.5 million a year in ongoing APCD maintenance, private carriers in CA collectively would need to spend about $34 million).

Therefore, implementing APCDs through the Form 5500 rule would impose significant costs on the government, and on the group health plans submitting the data

Issue – Ensuring Data Integrity

Maintaining the integrity and accuracy of centralized data is inherently challenging.

Recommendation:

Data integrity is enhanced when data are not removed from those who know them best and are best suited to assess and address any questions as to the integrity of the data.

Rationale:

Health care data is rife with often incompatible medical standards and coding schemes that require careful translation. Even an individual data provider's data is likely to come from many sources and be delivered in several tape or data formats. The industry's widely decentralized and largely autonomous data collection efforts make data quality a significant challenge. When data are copied from multiple sources and then analyzed centrally, the burden of data processing falls on the analyzing institution, resulting in inefficient data cleaning. Because the only "source of truth" is the original source, there are large collections of errors (variant diagnoses, incompatible test results, and changes in coded data) that cannot be fixed without a deep understanding of the underlying source data.

Even if centralized data are highly curated and extensively scrubbed – which we believe is not the case for a number of today's state APCDs – issues come up where it is essential to call on the people who produced the data, which is difficult to do when the data are centralized. Mark McClellan made this point when he commented on CMS's original proposal to centralize data for risk adjustment: relative to a distributed model (which we discuss in more detail below), a third party's centralized model that aggregates data across multiple payers is at a disadvantage in assuring data consistency and quality, because the data are removed from those who know them best and are thus best suited to assess and address any idiosyncrasies or anomalies. Standardizing data elements—an essential requirement for functional risk adjustment—is best done by those who know the data best. In a centralized model, data inconsistencies that are not obvious are likely to be missed.[1]

[1] Mark B. McClellan, "Comments on Proposed Rule, Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment," Letter to CMS (October 31, 2011).

Issue – APCDs and ERISA's Purposes

Whether APCDs are an appropriate tool for carrying out the purposes of ERISA.

Recommendation:

APCDs are a poor tool for implementing ERISA and should not be used for that purpose.

Rationale:

As noted above, the primary stated purposes of APCDs and the purposes of ERISA are different, which itself calls into question bootstrapping any kind of APCD proposal to the Form 5500. Indeed, the National Academy for State Health Policy has cited as illustrative examples of the ways APCDs are being used analyses focused on Medicaid (*e.g.,* NH used APCD data to measure access to and utilization of preventive services, such as cancer screening or diabetic testing and treatment, among its adult Medicaid population) and on broader public health concerns (*e.g.,* various states have used APCDs to track population-wide trends in utilization and cost of specific services, or in spending generally).

Yet even if it could be argued that APCDs could relate to some ERISA purposes in theory, the reality of APCD data, and how they have been used (or not used) raises serious doubt about DOL placing any reliance on APCDs.

First, APCD data – even if they were to conform to the Common Data Layout – are subject to confounders and sources of bias that are not apparent in the data itself, that is, benefit design/product specifics, formulary positioning, UM/CM/DM participation, etc. Each of these changes the meaning of data within these databases, rendering invalid the results of many queries or studies.

Second, about half of today's 13 fully-functioning APCDs are not active. According to the APCD Council:

- 3 states have not generated any published research or analysis (AR, TN, RI).
- 2 states (UT and MN) have produced no reports since 2014 – nor have those states taken any action based on these older reports.

Third, among the states actively using APCDs, a major objective is promoting cost and quality transparency by building cost- and quality-transparency tools. Yet these efforts are superfluous because private payers have taken a leading role in engaging consumers by providing them the right amount and level of information so they can make informed decisions and become more active partners in their health and the management of their care. Private payers, not states, are best positioned to give consumers transparency tools. The Healthcare Financial Management Association's Price Transparency Task Force reports that health plans have the most comprehensive understanding of price in today's healthcare marketplace, and are best situated to provide price information to their members. "Many health plans already offer tools that

provide price and quality information to their members…. *To provide the most helpful price information, these tools should be tied to the specifics of an individual's benefit design and include information on applicable copayment, coinsurance, or deductible requirements* [emphasis added]. They should also assist members in identifying in-network providers and identify any impact that selection of an out-of-network provider is expected to have on the patient's responsibility for payment."

Finally, little to no evidence is available showing that APCDs have been integral to improving the quality, cost, and transparency of health care for states' insured populations. Yes, some of the states with APCDs have generated reports, yet states have been hard pressed to show that policymakers have taken any policy actions in response to these reports. For example, it is telling that at the June 17, 2016, National Committee for Vital and Health Statistics (NCVHS) hearing on APCDs, a member of the Committee asked the representatives of two states with APCDs (CO and MA) to provide "a specific case that would address [the] concern of where somebody has actually used this real-life, real-data to make a policy change?" Neither provided a strong example. The representative for CO responded "APCDs are very new. We are continuing to gather the information…we are on the cusp." (The Center for Improving Value in Health Care that runs CO's APCD has been releasing data analyses since at least 2013.) The MA representative (whose APCD began collecting claims in 2008) agreed with CO that "we are on the cusp," and provided only one "simple" cost savings involving administrative simplification: "we are trying to offload some of the state reporting requirements from the payers since we have the data. We will produce it for them. That way, they can have a reduction in their resources in developing multiple reports from multiple state agencies."

Issue – Ensuring Data Privacy and Security

Adding enrollee-level claims data to Schedule J would raise new HIPAA privacy and security concerns.

Recommendation:

If data collection is required, it should not be done on a centralized basis due to the increased risk of privacy and security breaches.

Rationale:

Adding enrollee-level claims data to Schedule J would raise new HIPAA privacy and security concerns, because it necessarily would force new requirements on the ERISA groups that would be the conduits for submitting data. Pre-*Gobeille*, the enrollee-level claims data sent to a state APCD may never have been seen by the employer, only its TPA; but if DOL bootstraps Schedule J to support APCDs, it will force employers to handle PII and PHI that they may have no interest in touching or – because they do not now meet the necessary HIPAA privacy and security rules – ability to handle.

Fully-insured plans are generally not subject to certain HIPAA requirements where the employer does not have any access to PHI. If enrollee-level data, such as that generally collected by

APCDs, is required to be filed as part of the Form 5500 (which is a filing obligation of the plan, not the insurer), then the plan would need to adopt much more robust privacy and security procedures and ensure compliance with HIPAA generally. One of the main reasons an employer may choose an insured plan is so that it can rely on the insurer to handle these types of privacy and security obligations.

Self-insured plans are not carved out of many of HIPAA's provisions like fully-insured plans. However, as a practical matter, many self-insured plans structure their service provider agreements so that the service providers have access to PHI and the plan itself does not receive PHI. This would limit exposure under HIPAA. As noted above, if an APCD were implemented by the DOL, the plan would need to adopt much more robust privacy and security procedures and ensure compliance with HIPAA generally.

If sensitive information is being gathered by plans and filed with the DOL on an annual basis, the likelihood of a HIPAA breach increases significantly. Collecting and storing data from multiple health plans is unsafe because once data are transmitted they become vulnerable to security and privacy violations. Instead, leaving physical possession of claims data with the plans can reduce the risk and severity of data breach. Indeed, privacy is one of the main reasons that CMS decided in the final rule on risk mitigation to rely on a "distributed data" approach (discussed below) rather than a centralized approach: "The transmission by issuers to HHS and the storage by HHS of large amounts of sensitive data pose potential risks to consumer privacy. A *distributed approach* [emphasis added] would leverage the existing data infrastructure of issuers, potentially saving Federal and issuer resources. For these reasons, HHS will utilize a distributed approach to collecting risk adjustment data when operating risk adjustment on behalf of a State."

Issue – Proprietary Information at Risk

Collecting and centralizing patient-specific claims data could impede market competition by revealing sensitive proprietary information.

Recommendation:

It is important for companies to maintain the secrecy of proprietary information in order to compete in the marketplace.

Rationale:

Competition will suffer and costs will rise if, for example, privately contractually negotiated discounts between payers and providers are disclosed. Yet Forms 5500 are publicly available.

At a minimum, therefore, DOL would have to specify that any enrollee-specific data will be kept confidential. However, that would paradoxically undermine the financial sustainability of many state APCDs, which rely on selling APCD data to generate funding for the APCD. For example, the State of Colorado mandated the creation of the CO APCD and did not appropriate any tax

payer dollars – in order to be sustainable and operational, the organization that run's CO's APCD releases non-public data to recoup costs.

Moreover, data collected by DOL could be subject to public release under the Freedom of Information Act (FOIA) rules despite any rule to the contrary. This exposes health plans to the significant risk that proprietary data would be released as the result of a FOIA request. It also raises privacy concerns, because even if data are de-identified, that will not necessarily protect individuals from having their sensitive medical information publicly exposed because of sophisticated re-identification and de-anonymization threats. For example, research has shown that between 2.3% and 6.1% of individuals could be identified from prescription records that did not include the patient's name or address using prescription information: drug, dosage and refill information, patient diagnosis, patient ZIP Code inferred from pharmacy ZIP Code, and prescription fill date.

Issue – Alternatives to Centralizing Data

Use of a distributed data approach as an alternative to a centralized data repository.

Recommendation:

If DOL or the Government needs enrollee-level, patient-specific data, there is an alternative approach that is not fraught with the same problems as a centralized data repository: a distributed data approach.

Rationale:

In general, so-called distributed or federated models provide a proven alternative to centralized data collection. A distributed network can perform essentially all the functions desired of a centralized database, while avoiding many disadvantages of centralized databases:

1. They allow data holders to maintain physical control over their data.

2. They ensure ongoing participation of individuals who are knowledgeable about the systems and practices that underlie each data holder's data.

3. They allow data holders to assess and authorize query requests, or categories of requests, on a user-by-user or case-by-case basis.

4. Distributed systems minimize the need to disclose protected health information thus mitigating privacy concerns, many of which are regulated by the Privacy and Security Rules of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

5. Distributed systems minimize the need to disclose and lose control of proprietary data.

6. A distributed approach eliminates the need to create, secure, maintain, and manage access to a complex central data warehouse.

7. Finally, a distributed network also avoids the need to repeatedly transfer and pool data to maintain a current database, which is a costly undertaking each time updating is necessary

8. The federal government has already adopted a distributed approach in two important programs: the FDA's "Sentinel" system; and CMS's "Edge Servers."

The FDA's Distributed Sentinel Model

The FDA Amendment Act of 2007 required FDA to create the capability to use electronic health data from at least 100 million people to assess the safety of marketed medical products. The FDA responded by building today's distributed Sentinel System.

Sentinel now has more than 358 million person-years of data – including 4.0 billion prescriptions, 4.1 billion doctor or lab visits and hospital stays, and 42.0 million acute inpatient stays – which derive primarily from medical bills (claims), but a growing portion comes from EHRs or laboratory results (approximately 10 percent) – a portion expected to grow steadily in coming years.

Among its data partners are Anthem BCBS, BCBSMA, Kaiser Permanente, Humana, and Aetna. After creating a common data model, the FDA established a distributed analysis platform: users create and submit query (a computer program); data partners retrieve query; data partners review and run query against their local data; data partners review results; data partners return results via secure network.

The FDA has taken Sentinel beyond safety surveillance. For example, the FDA wanted to look at atrial fibrillation ("AF") because it is a major public health problem (*i.e.,* it increases risk of stroke, oral anticoagulation reduces risk, but many people for whom anticoagulation is recommended do not take it). FDA sent a rapid query to three data partners, looking at data for 16 million members over January 2006 to June 2014. The analysis found that 202,000 had AF plus additional risk factors, and 48 percent had no record of oral anticoagulant dispensing. This has led to the IMPACT-AF trial, a randomized trial under development to improve treatment with anticoagulants in people with AF.

CMS Risk Adjustment and EDGE Servers

A distributed data infrastructure containing claims information on more than 30 million lives in the individual and small group markets is already operating in every state.

In deciding how to obtain and process claims data for ACA reinsurance and risk adjustment calculations, CMS rejected a centralized approach in favor of a distributed data collection model – CMS found that it proved the most effective approach because such a model would ensure minimal transfer of protected health information between issuers and CMS, thereby lowering privacy and data security risks; and standardization of business processes, timing and rules.

CMS implemented the distributed data approach through External Data Gathering Environment or “EDGE” servers. Issuers upload enrollee, pharmaceutical claim, medical claim, and supplemental diagnosis information from their proprietary systems to an issuer-owned and controlled EDGE server. (Issuers have the option to own and operate the server themselves, or to have a third-party entity operate the server.) The EDGE server runs CMS-developed software designed to verify submitted data and execute the risk adjustment and reinsurance processes. Detailed data, file processing metrics, and outbound data files are provided to issuers, while only plan-summarized data and file processing metrics are provided to CMS. CMS does not receive any individual-level data as part of this process.

Consistent with the requirements under the Paperwork Reduction Act, a distributed approach is less burdensome than a centralized data collection approach for achieving any program objectives that depend on enrollee-level, patient-specific data.